

Criteria for Nonformulary Use of Cinacalcet

VA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient.

Refer to the National PBM Drug Monograph Cinacalcet HCl (Sensipar™) at <http://www.vapbm.org/monograph/43895Cinacalcet.pdf> or <http://vaww.pbm.med.va.gov> for recommendations on dosing, precautions, and monitoring

Exclusion Criteria		#1
[†] Serum calcium < 8.4mg/dl ^a		[†] yes [†] no <i>If yes, patient is not eligible to receive cinacalcet</i>
Diagnoses		#2
Cinacalcet should only be used for patients who do not meet the exclusion criteria above and who have one of the following diagnoses in addition to at least one of the criteria in Section #3: [†] Secondary Hyperparathyroidism in a patient with chronic kidney disease on chronic dialysis ^{1,2} OR [†] Parathyroid Carcinoma ² prior to surgical intervention; in a patient who is not a surgical candidate; or recurrence despite surgical intervention		[†] yes [†] no <i>If yes (and no for #1), patient is eligible to receive cinacalcet IF they meet ≥ 1 of the criteria in #3</i>
Criteria for Use		#3
[†] Intact plasma parathyroid hormone (iPTH) level > 400 pg/ml ³ [or Bio-Intact (full-length) PTH > 200 pg/ml ³] in addition to A. OR B.: A. iPTH level > 400 pg/ml ³ despite maximal tolerated doses of all forms of phosphate binders ^{b,c} and vitamin D ^d B. Calcium x phosphorus product > 55mg ² /dl ² [†] 1 despite dietary restriction of phosphate to < 1gm/d AND [†] 2 trial of calcium based phosphate binders ^b AND [†] 3 then addition of or change to sevelamer ^c As cinacalcet may lower serum calcium, adjustment of phosphate binders may be required (i.e., sevelamer should be reduced with a goal of discontinuation, if possible, and calcium based binders adjusted to control phosphorus as indicated ^b) OR [†] Total serum calcium (corrected for serum albumin) ^a ≥ 10.2mg/dl (or maximum per lab/facility) in a patient with parathyroid carcinoma despite standard therapy to control hypercalcemia		[†] yes [†] no <i>If yes to #3 and #2 (and no for #1), patient is eligible to receive cinacalcet</i>

^aCalculation for corrected total serum calcium=total calcium + 0.8 (4 - serum albumin) [4gm/dl (normal serum albumin) – most recent serum albumin]
 The normal serum albumin of 4.0gm/dl is based on measurements using bromocresol green. If the bromocresol purple method is used, the normal serum albumin should be 3.5gm/dl.

Ex. Calcium 9.9mg/dl; albumin 3.2gm/dl

[4 – 3.2] = 0.8; 0.8 X 0.8 = 0.64

9.9 + 0.64 = 10.54 (10.5mg/dl is the corrected serum calcium)

^bK/DOQI Guideline recommendations are to limit elemental calcium intake from phosphate binders to < 1500mg/d (based on Opinion; corresponds to USPSTF Quality of Evidence Level III: refer to Harris RP, Helfand M, Woolf SH, et al. for the Methods Work Group, Third U.S. Preventive Services Task Force. Current methods of the U.S. Preventive Services Task Force. A review of the process. Am J Prev Med 2001;20(3S):21-35.)

^c Refer to Criteria for Nonformulary Use of Sevelamer Hydrochloride in VA Patients with Chronic Kidney Disease and Kidney Failure on Dialysis at <http://www.vapbm.org/criteria/Sevelamecriteria.pdf>

^dK/DOQI Guideline dosing recommendations for vitamin D if iPTH 600-1000pg/ml:³ IV calcitriol 1-3µg three times/ week, IV paricalcitol^c 6-10µg three times/week, IV doxercalciferol^c 2-4µg three times/week, or equivalent [in the absence of hypercalcemia (calcium > 10.2mg/dl^a) or hyperphosphatemia (phosphorus > 6.5mg/dl)]

^e Not listed on the VA National Formulary

References:

1. Block GA, Martin KJ, de Francisco ALM, et al. Cinacalcet for secondary hyperparathyroidism in patients receiving hemodialysis. N Engl J Med 2004;350:1516-25.
2. Sensipar™ (cinacalcet HCl) package insert. Thousand Oaks, CA: Amgen; 2004 Mar.
3. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Am J Kidney Disease 2003;42(suppl 3):S1-S202.

Approved by Physician: _____

Date/Time: _____